K091924

5. 510(k) Summary

Sponsor: VasoNova Inc.
1368 Bordeaux Drive
Sunnyvale, CA 94089

NOV 18 2009

Contact Person: Kim Tompkins
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Prepared: June 26, 2009

Trade Name: VPS Catheter, name subject to change
Common Name: Percutaneous, implanted, long-term intravascular catheter
Classification: II
Product Code: LJS 21 CFR 880.5970
Advisory Panel: General Hospital

Predicate Devices: VasoNova VPS Catheter
Bard Catheter
Medcomp Catheter

Device Description
The VPS Catheter is designed for use with or without the VPS Stylet and the VPS Console. When sold together, the VPS Catheter is preloaded with the Stylet and supplied in a tray. The VPS Catheter is sterile, single use, non-pyrogenic and non-toxic.

VPS Catheters are single lumen (3F and 4F) or dual lumen (5F) open-ended central venous access catheters fabricated from a soft, radiopaque, biocompatible polyurethane material with a working length of 50 or 55 cm and catheter markings at 1 cm intervals and 5 cm increments. VPS Catheters are packaged sterile with the VPS Stylet in a tray with accessories necessary for a percutaneous micro-introducer placement (Modified Seldinger or Seldinger technique). The VPS Catheters feature a reverse-taper design.

Intended Use
VPS catheters are indicated for short or long-term central or peripheral access to the central venous system for intravenous fluid and blood infusions, contrast studies with and without a power injector, central venous pressure monitoring, and blood sampling.

Performance Data
Previously provided *in vitro* and *in vivo* testing demonstrated that the subject device meets all acceptance criteria. Completed testing included:

- Static, burst and dynamic pressure
- Physical characteristics
- Flexural fatigue and flexibility
- Flow rate
- Flexural fatigue and flexibility
- Tensile and torque strength
- Freedom from air leakage
- Priming volume
- Mechanical hemolysis
- Collapsibility and elongation

Substantial Equivalence
VasoNova VPS Catheters have the same intended use, technological characteristics and principles of operation as its predicate devices. The subject and predicate catheters are similar in that they are labeled for central or peripheral access, deliver fluid and blood infusions, can be used for contrast studies, are appropriate for CVP monitoring and blood sampling. Previously provided performance data demonstrate that the subject device is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ms. Kim Tompkins, RN, MBA
Vice President, Regulatory/Quality/Clinical
VasoNova Incorporated
1368 Bordeaux Drive, Suite 100
Sunnyvale, California 94089

NOV 18 2009

Re: K091924
Trade/Device Name: VasoNova VPS Catheter
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: October 29, 2009
Received: October 30, 2009

Dear Ms. Tompkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. 510(k) Indications for Use

510(k) Number (if known): _____

Device Name: VasoNova VPS Catheter

Indications for use:

VPS Catheters are indicated for short or long-term central or peripheral access to the central venous system for intravenous therapy, central venous pressure monitoring and contrast studies. For blood or hyperalimentation delivery, use a 4F or larger catheter. The maximum recommended injection rate is 2cc/sec for the 3F catheter and 5cc/sec for the 4F and 5F catheters. Each VPS Catheter is indicated for use by itself or with the VPS System (Stylet and Console).

Prescription Use X OR Over-the-Counter Use _____
(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K991924